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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/187,661	11/06/1998	BRET A. SHIRLEY	5784-3	3329

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/187,661

Applicant(s)

SHIRLEY ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,13,16-20 and 28-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,13,16-20 and 28-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 1, 3, 4, 13, 16-20 and 28-47 are pending.

Applicants' amendment filed July 15, 2003 (Paper No. 31) is acknowledged, and applicants' response has been fully considered. Claims 1, 16, 34 and 42 have been amended, and new claims 45-47 have been added, thus claims 1, 3, 4, 13, 16-20 and 28-47 are examined.

Rejection Withdrawn

Claim Rejections-Obviousness Type Double Patenting

2. The previous rejection of claims 1, 3, 4, 13, 16-20 and 28-44 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-9, 12-16 and 26-51 of copending Application No. 09/187,780, is withdrawn in view of applicants' submission of the terminal disclaimer, and applicants' response at page 6 in Paper No. 31.

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 1, 3, 4, 13, 16-20 and 28-44, under 35 U.S.C.112, second paragraph, regarding the term "at least about 250 mg/ml" or "greater than about pH 5.0" is withdrawn in view of applicants' amendment of the claim, and applicants' response at page 8 in Paper No. 31.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 3, 4, 13, 16-20 and 28-47 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-48 and 85-112 of copending Application No. 09/188,051. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 3, 4, 13, 16-20 and 28-47 in the instant application disclose a low salt-containing aqueous composition comprising biologically active human IGF-I or a functional variant thereof in a concentration of about 250 mg/ml and a pH about 5.0 or greater, wherein the variant has at least 80% sequence identity to human IGF-I. This is obvious in view of claims 29-48 and 85-112 in the copending application which disclose a composition having a pH of 5.5 or greater, comprising IGF-I or a biologically active analog thereof having at least 70% sequence identity to human IGF-I at a concentration of about 12 mg/ml to about 200 mg/ml, and at a temperature of about 4 °C, and a solubilizing compound comprising a guanidinium group, wherein the solubilizing compound is in an amount sufficient to make IGF-I or analog thereof soluble. Since the low salt-containing composition can be a composition containing a salt such as arginine or other arginine compounds in an amount that makes IGF-1 or its analog more soluble at higher concentration and at about 4 °C, and the concentration of IGF-1 is about 250 mg/ml, thus, both sets of claims encompass a low salt-containing (e.g., arginine) aqueous composition comprising human IGF-I or a biologically active variant thereof at a concentration of about 250 mg/ml and a pH about 5.5 or greater,

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wherein the variant has at least 80% sequence identity to human IGF-I. Thus, claims 1, 3, 4, 13, 16-20 and 28-47 in present application and claims 29-48 and 85-112 in the copending application are obvious variations of a low salt-containing (e.g., arginine) aqueous composition comprising human IGF-I or a biologically active variant thereof at a concentration of about 250 mg/ml and a pH about 5.5 or greater, wherein the amount of arginine compound makes IGF-I or its analog more soluble at about 4 °C.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response, applicants indicate the present claims are directed to low salt-containing, highly concentrated compositions with IGF-I at a concentration of about 250 mg/ml or greater, as indicated in the specification, these compositions contain IGF-I in the form of a highly concentrated syrup, which is obtained from removing the solubility enhancer; while the claims of 09/188,051 are directed to the compositions comprising a solubilizing compound and the IGF-I is present at a concentration of about 12 mg/ml to about 200 mg/ml, thus, the composition in the 051' application do not suggest the claimed composition in the instant application (page 7 of the response). The response has been fully considered, however the argument is not found persuasive because the claims in the instant application cite the concentration of IGF-I is about 250 mg/ml, which can be 200 mg/ml because the specification does not define the range for "about". Furthermore, the claims of the instant application do not indicate IGF-I is in the syrup form and the solubility enhancer has been removed, thus the composition of the claimed invention is not distinct from the composition cited in the claims of 051' application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 16, 19, 38-41, 43 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 38, 40 and 43 are indefinite because of the use of the term “and/or”. The term “and/or” renders the claim indefinite, it is unclear whether the limitation after “and/or” is included or not, and if included is to be read as an alternative “or” or the conjunctive “and”.

In response, claim 16 has been amended to delete the term “and/or”, however, claims 38, 40 and 43 still contain this term.

7. Claims 19, 39, 41 and 44 are indefinite, it is unclear what the term “PLGA” means. A fully spelled out word should be indicated at the first occurrence.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

September 23, 2003



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